IN THE UNITED STATES DISTRICT COURT DISTRICT OF DELAWARE

In re: Seroquel XR (Extended Release Quetiapine Fumarate) Antitrust Litigation

This Document Relates To:

All Direct Purchaser Class Actions

Master Dkt. No. 20-1076-CFC

DEFENDANT ASTRAZENECA'S ANSWER TO DIRECT PURCHASER'S CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

Defendants AstraZeneca Pharmaceuticals L.P. and AstraZeneca L.P. (together, "AstraZeneca"), by counsel, hereby file their Answer to Direct Purchaser Plaintiffs' Consolidated Amended Class Action Complaint (D.I. 1) ("Complaint"). All responses are based solely on the knowledge and information of AstraZeneca. Unless otherwise stated, AstraZeneca does not purport to admit or characterize the conduct of any other defendant. To the extent the headings or footnotes in the Complaint contain factual allegations to which a response is required, they are denied. All other allegations not specifically admitted are denied. AstraZeneca reserves the right to amend its Answer, in whole or in part.

1. The allegations in the last sentence of Paragraph 1 of the Complaint do not concern AstraZeneca, and thus AstraZeneca is not required to respond. The remaining allegations in Paragraph 1 consist of Plaintiffs' characterization of their

purported claims, to which no answer is required. To the extent an answer is required, AstraZeneca refers Plaintiffs to the FDA prescribing information for Seroquel XR and denies Plaintiffs' characterization of it. AstraZeneca otherwise denies that it engaged in anticompetitive conduct, denies that it entered into an unlawful agreement with Handa or Accord, denies that Plaintiffs are entitled to any damages or other relief, and denies the remaining allegations in Paragraph 1 of the Complaint. Further, as to Accord, under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. To the extent an answer is required in response to allegations concerning the "Accord/AstraZeneca agreement," AstraZeneca denies those allegations.

- 2. The allegations in Paragraph 2 of the Complaint are vague and unclear, and AstraZeneca therefore lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 and on that basis denies them.
- 3. As to Accord, under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca

agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. AstraZeneca refers Plaintiffs to the referenced final approval letters and ANDAs for their contents, denies Plaintiffs' characterization of them, and otherwise denies the allegations in Paragraph 3 of the Complaint.

- 4. As to Accord, under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. AstraZeneca refers Plaintiffs to the cited stipulated facts for their contents, denies Plaintiffs' characterization of them, an otherwise denies the allegations in Paragraph 4 of the Complaint.
- 5. AstraZeneca refers to the '437 patent for its contents and denies Plaintiffs' characterization of it.
- 6. AstraZeneca refers Plaintiffs to the cited complaint for its contents and denies Plaintiffs' characterization of it.
- 7. AstraZeneca refers Plaintiffs to the cited complaint for its contents and denies Plaintiffs' characterization of it.
- 8. AstraZeneca refers Plaintiffs to the cited complaint for its contents and denies Plaintiffs' characterization of it.

- 9. AstraZeneca refers Plaintiffs to the referenced lawsuits' complaints for their contents and denies Plaintiffs' characterization of them. The remaining allegations in Paragraph 9 consist of Plaintiffs' characterization of their purported claims, to which no answer is required, and to the extent an answer is required, the remaining allegations are denied.
- 10. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. To the extent a response is required, AstraZeneca refers Plaintiffs to the referenced lawsuits for their contents and denies Plaintiffs' characterization of them. The remaining allegations in Paragraph 10 consist of Plaintiffs' characterization of their purported claims, to which no answer is required, and to the extent an answer is required, the remaining allegations are denied.
- 11. AstraZeneca refers to the referenced Handa Seroquel XR Patent
 Litigation, including all related filings and holdings, for its contents and denies
 Plaintiffs' characterization of that litigation, and otherwise denies the allegations in
 Paragraph 11 of the Complaint.

- 12. AstraZeneca refers Plaintiffs to the referenced claim construction opinion for its contents and denies Plaintiffs' characterization of it.
- 13. As to the allegations in the first sentence of Paragraph 13, AstraZeneca refers to FDA's December 9, 2010 tentative approval letter for its contents and denies Plaintiffs' characterization of it. As to the remaining allegations in Paragraph 13, AstraZeneca refers to the Hatch-Waxman Act and the Federal Food, Drug, and Cosmetic Act, as amended, for their contents, denies Plaintiffs' characterization of them, and otherwise denies the allegations in Paragraph 13 of the Complaint.
- 14. AstraZeneca refers to the cited claim construction opinion for its contents, denies Plaintiffs' characterization of it, and otherwise denies the allegations in Paragraph 14 of the Complaint.
- 15. AstraZeneca refers Plaintiffs to the cited settlement agreement for its contents, denies Plaintiffs' characterization of it, and otherwise denies the allegations in Paragraph 15 of the Complaint.
- 16. The allegations in Paragraph 16 concerning what Handa "would not have agreed to" do not concern AstraZeneca, and thus AstraZeneca is not required to respond. To the extent an answer is required as to what Handa "would not have agreed to," AstraZeneca lacks knowledge or information sufficient to form a belief

as to the truth of those allegations, and denies the allegations on those grounds.

AstraZeneca denies any remaining allegations in Paragraph 16 of the Complaint.

- 17. AstraZeneca refers Plaintiffs to the cited press release for its contents and denies Plaintiffs' characterization of it.
- AstraZeneca, and thus AstraZeneca is not required to respond. To the extent an answer is required, AstraZeneca refers Plaintiffs to the referenced press release for its contents and denies Plaintiffs' characterization of it. Further, the allegations in the last sentence of Paragraph 18 set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in last sentence in Paragraph 18. AstraZeneca otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 18 and on that basis denies them.
- 19. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. To the extent a response is required, as to the first sentence in Paragraph 19, AstraZeneca refers Plaintiffs to the cited settlement agreement for its contents, denies Plaintiffs' characterization of it, and

otherwise denies the allegations in Paragraph 19 of the Complaint. The remaining allegations in Paragraph 19 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 19 of the Complaint.

- 20. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. Further, the allegations in Paragraph 20 concerning what Accord "would not have agreed to" do not concern AstraZeneca, and thus AstraZeneca is not required to respond. To the extent an answer is required, AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of those allegations. AstraZeneca denies remaining allegations in Paragraph 20 of the Complaint.
- 21. As to Accord, under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. Further, the allegations in Paragraph

21 of the Complaint do not concern AstraZeneca, and thus AstraZeneca is not required to respond. To the extent an answer is required, AstraZeneca refers Plaintiffs to the referenced article for its contents and denies Plaintiffs' characterization of it.

- 22. AstraZeneca refers Plaintiffs to the cited article and denies Plaintiffs' characterization of it.
- 23. The allegations in Paragraph 23 do not concern AstraZeneca, and thus AstraZeneca is not required to respond. To the extent an answer is required, the allegations in Paragraph 23 are vague and AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of those allegations, and denies the allegations on those grounds.
 - 24. AstraZeneca denies the allegations in Paragraph 24 of the Complaint.
- 25. For the legal proposition cited by Plaintiffs, AstraZeneca refers them to *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 751-52 (E.D. Pa. 2014) for its contents and denies Plaintiffs' characterization of that case. AstraZeneca denies the remaining allegations in Paragraph 25 of the Complaint.
- 26. As to Accord, under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the

"Accord/AstraZeneca agreement" is required. To the extent a response is required, AstraZeneca denies the allegations related to the "Accord/AstraZeneca agreement." Further, the allegation that any conduct "resulted in anticompetitive overcharges to Plaintiffs and members of the Class" is a legal conclusion to which no answer is required. To the extent an answer is required to that legal conclusion, AstraZeneca denies the allegation. AstraZeneca denies the remaining allegations in Paragraph 26 of the Complaint.

- 27. The allegations in Paragraph 27 set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 27.
- 28. The allegations in Paragraph 28 set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 28.
- 29. The allegations in Paragraph 29 consist of Plaintiffs' characterization of their purported claims, to which no answer is required. To the extent an answer is required, AstraZeneca denies that Plaintiffs are entitled to any damages, attorneys' fees or other relief and denies the remaining allegations in Paragraph 29 of the Complaint.
- 30. As to AstraZeneca alone, AstraZeneca denies that it conducted business as "hereinafter described" in the Complaint, but it admits that it conducts

trade and business in the district. As to any remaining allegations in Paragraph 30 concerning other Defendants, AstraZeneca is not required to respond, nor does it have knowledge or information sufficient to form a belief as to the truth of those allegations.

- 31. The allegations in Paragraph 31 set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 31.
- 32. The allegations in Paragraph 32 set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 32.
- 33. The allegations in Paragraph 33 set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 33.
- 34. As to AstraZeneca alone, AstraZeneca admits only the allegation in Paragraph 34 of the Complaint that the Court has personal jurisdiction over AstraZeneca. AstraZeneca denies all remaining allegations in Paragraph 34, including that it "committed overt acts in furtherance of its illegal conduct and conspiracy." Further, as to any remaining allegations in Paragraph 34 concerning other Defendants, AstraZeneca is not required to respond, nor does it have

knowledge or information sufficient to form a belief as to the truth of those allegations.

- 35. AstraZeneca admits that J M Smith Drug Corporation d/b/a Smith Drug Company ("Smith Drug Company") purchased branded Seroquel XR on one or more occasions after August 2, 2015. AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of Plaintiff Smith Drug Company's principal place of business, state of incorporation, corporate structure, or purchases from Par, and on that basis denies those allegations. The remaining allegations in Paragraph 35 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the remaining allegations in Paragraph 35.
- 36. AstraZeneca admits that KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc. purchased branded Seroquel XR on one or more occasions after August 2, 2015. AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of Plaintiff Kinney Drugs, Inc. principal place of business, state of incorporation, corporate structure, assignment of claims, or purchases from Par, and on that basis denies those allegations. The remaining allegations in Paragraph 36 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the remaining allegations in Paragraph 36.

- 37. AstraZeneca admits that AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of Delaware, with a principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.
- 38. AstraZeneca denies that AstraZeneca LP is a Delaware limited partnership with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.
- 39. AstraZeneca denies that AstraZeneca UK Limited is a company operating and existing under the laws of the United Kingdom, with its principal place of business at 15 Stanhope Gate, London, United Kingdom W1Y 6LN.
- 40. AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 40 of the Complaint and on that basis denies them.
- 41. AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 41 of the Complaint and on that basis denies them.
- 42. The allegations in Paragraph 42 set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 42.
- 43. The allegations in Paragraph 43 of the Complaint consist of Plaintiffs' characterization of their purported claims, to which no answer is required. To the

extent an answer is required, AstraZeneca acknowledges that Plaintiffs purport to bring this action on behalf of themselves and a purported class but AstraZeneca denies that this action meets the requirements for a class action under Federal Rule of Civil Procedure 23 and denies the remaining allegations in Paragraph 43.

- 44. The allegations in Paragraph 44 set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 44.
- 45. The allegations in Paragraph 45 set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 45.
- 46. The allegations in Paragraph 46 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 46 and on that basis denies them.
- 47. The allegations in Paragraph 47 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 47 and on that basis denies them.

- 48. The allegations in Paragraph 48 set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 48.
- 49. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. To the extent a response to any allegations related to the "Accord/AstraZeneca agreement" is required, AstraZeneca denies those allegations. The remaining allegations in Paragraph 49 set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the remaining allegations in Paragraph 49.
- 50. The allegations in Paragraph 50 set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 50.
- 51. AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 51 of the Complaint and on that basis denies them.
- 52. AstraZeneca refers to the referenced law for its content and denies Plaintiffs' characterization of it.

- 53. AstraZeneca refers to the referenced law for its content and denies Plaintiffs' characterization of it.
- 54. AstraZeneca refers to the Hatch-Waxman Act and the Federal Food, Drug, and Cosmetic Act, as amended, for their content and denies Plaintiffs' characterization of them. AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 54 and on that basis denies them.
- 55. AstraZeneca refers to the referenced law for its content and denies Plaintiffs' characterization of it.
- 56. AstraZeneca refers to the referenced law for its content and denies Plaintiffs' characterization of it. AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of allegations concerning the purported statistics and, on that basis, denies them.
- 57. AstraZeneca refers to the referenced law for its content and denies Plaintiffs' characterization of it.
- 58. AstraZeneca refers to the referenced law for its content and denies Plaintiffs' characterization of it.
- 59. AstraZeneca refers to the referenced law for its content and denies Plaintiffs' characterization of it.

- 60. AstraZeneca refers to the referenced law for its content and denies Plaintiffs' characterization of it.
- 61. AstraZeneca refers to the Hatch-Waxman Act and the Federal Food, Drug, and Cosmetic Act, as amended, for their content, denies Plaintiffs' characterization of them and otherwise denies the allegations in Paragraph 61 of the Complaint.
- 62. AstraZeneca refers to the referenced law for its content and denies Plaintiffs' characterization of it.
- 63. AstraZeneca refers to the Hatch-Waxman Act and the Federal Food, Drug, and Cosmetic Act, as amended, for their content, denies Plaintiffs' characterization of them and otherwise denies the allegations in Paragraph 63 of the Complaint.
- 64. AstraZeneca refers to the quoted Supreme Court opinion for its content and denies Plaintiffs' characterization of it.
- 65. AstraZeneca refers to the Hatch-Waxman Act and the Federal Food, Drug, and Cosmetic Act, as amended, for their content, denies Plaintiffs' characterization of them and otherwise denies the allegations in Paragraph 65 of the Complaint.
- 66. AstraZeneca refers to the Hatch-Waxman Act and the Federal Food, Drug, and Cosmetic Act, as amended, for their content, denies Plaintiffs'

characterization of them and otherwise denies the allegations in Paragraph 66 of the Complaint.

- 67. The allegations in Paragraph 67 of the Complaint are vague and speculative, and AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 67 and on those bases denies them.
- 68. The allegations in Paragraph 68 of the Complaint are vague and speculative, and AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 68 and on those bases, AstraZeneca denies them.
- 69. AstraZeneca refers to the referenced laws for their content and denies Plaintiffs' characterization of them. The remaining allegations in Paragraph 69 of the Complaint are vague and AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of those allegations and on those bases denies them.
- 70. AstraZeneca refers to the cited documents for their content and denies Plaintiffs' characterization of them. The allegations in the last sentence of Paragraph 70 are vague and AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of those allegations and on those bases denies them. AstraZeneca denies the remaining allegations in Paragraph 70.

- 71. The allegations in Paragraph 71 of the Complaint are vague and AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of those allegations and on those bases, AstraZeneca denies them.
- 72. AstraZeneca refers to the cited document for its content and denies Plaintiffs' characterization of it. The allegations in the first and second sentences of Paragraph 72 are vague and AstraZeneca lacks knowledge or information sufficient to form a belief as to their truth and on those bases denies them.

 AstraZeneca denies the remaining allegations in Paragraph 72.
- 73. The allegations in Paragraph 73 of the Complaint are vague and AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 73 and on those bases denies them.
- 74. The allegations in Paragraph 74 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 74.
- 75. The allegations in Paragraph 75 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 75.

- 76. AstraZeneca refers to the Hatch-Waxman Act and the Federal Food, Drug, and Cosmetic Act, as amended, and the referenced court opinions for their content and denies Plaintiffs' characterization of them. The remaining allegations in Paragraph 76 of the Complaint are vague, and to the extent not vague, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the remaining allegations in Paragraph 76.
- 77. AstraZeneca refers to the referenced FTC report for its content and denies Plaintiffs' characterization of it.
- 78. AstraZeneca refers to the cited documents for their content and denies Plaintiffs' characterization of them. The remaining allegations in Paragraph 78 of the Complaint are vague, and to the extent not vague, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the remaining allegations in Paragraph 78.
- 79. The allegations in the first sentence of Paragraph 79 of the Complaint are vague, and to the extent not vague, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in the first sentence of Paragraph 79. As to the second sentence of Paragraph 79, AstraZeneca refers to the referenced FTC report for its content and denies Plaintiffs' characterization of it.

- 80. The allegations in Paragraph 80 of the Complaint are vague, and to the extent not vague, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 80.
- 81. AstraZeneca refers to the referenced agreements for their terms and denies Plaintiffs' characterization of it. The remaining allegations in Paragraph 81 set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the remaining allegations in Paragraph 81.

 Moreover, as to Accord, under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. To the extent a response is required, AstraZeneca denies the allegations related to the "Accord/AstraZeneca agreement" on this ground as well.
- 82. The allegations in Paragraph 82 of the Complaint are vague and speculative and AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 82 and on those bases denies them.

- 83. The allegations in Paragraph 83 of the Complaint are vague and speculative and AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 83 and on those bases denies them.
- 84. The allegations in Paragraph 84 do not concern AstraZeneca, and thus AstraZeneca is not required to respond. To the extent an answer is required, AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 84 and on those bases denies them. Further, as to Accord, under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. To the extent a response is required, AstraZeneca denies the allegations related to the "Accord/AstraZeneca agreement" on this ground as well.
- 85. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. Further, the allegations in Paragraph

85 further do not concern AstraZeneca, and thus AstraZeneca is not required to respond. To the extent an answer is required, AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 85 and on those bases denies them.

- 86. The allegations in Paragraph 86 do not concern AstraZeneca, and thus AstraZeneca is not required to respond. To the extent an answer is required, AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 86 and on those bases denies them.
- 87. The allegations in Paragraph 87 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 87.
- 88. The allegations in Paragraph 88 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 88.
- 89. The allegations in Paragraph 89 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 89.

- 90. AstraZeneca refers to the Hatch-Waxman Act and the Federal Food, Drug, and Cosmetic Act, as amended, for their content, denies Plaintiffs' characterization of them and otherwise denies the allegations in Paragraph 90 of the Complaint.
- 91. The allegations in Paragraph 91 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 91.
- 92. AstraZeneca admits that AstraZeneca Pharmaceuticals LP is the holder of NDA No. 22-047. AstraZeneca refers Plaintiffs to that NDA for its terms, and denies Plaintiffs' characterization of it.
- 93. AstraZeneca admits that it is the owner of U.S. Patent No. 4,879,288 ("the '288 Patent"). AstraZeneca refers Plaintiffs to the '288 Patent and referenced PTE for their contents and denies Plaintiffs' characterization of them.
- 94. AstraZeneca admits that it is the owner of the '437 Patent.

 AstraZeneca refers Plaintiffs to that patent for its contents and denies Plaintiffs' characterization of it.
- 95. AstraZeneca refers Plaintiffs to the FDA Orange Book and the referenced patents for their contents and denies Plaintiffs' characterization of them.
- 96. AstraZeneca refers Plaintiffs to the FDA Orange Book and the referenced patent for their contents and denies Plaintiffs' characterization them.

The allegations in Paragraph 96 of the Complaint otherwise are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 96.

- 97. AstraZeneca refers Plaintiffs to the referenced patent for its content and denies Plaintiffs' characterization of it. The allegations in Paragraph 97 of the Complaint otherwise set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 97.
- 98. The allegations in Paragraph 98 do not concern AstraZeneca, and thus AstraZeneca is not required to respond. To the extent an answer is required, AstraZeneca refers Plaintiffs to the referenced ANDAs for their content and denies Plaintiffs' characterization them.
- 99. The allegations in Paragraph 99 do not concern AstraZeneca, and thus AstraZeneca is not required to respond. To the extent an answer is required, AstraZeneca refers Plaintiffs to the referenced ANDA for their content and denies Plaintiffs' characterization of them.
- 100. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement";

accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. Further, the allegations in Paragraph 100 do not concern AstraZeneca, and thus AstraZeneca is not required to respond. To the extent an answer is required, AstraZeneca refers Plaintiffs to the referenced ANDA for their content and denies Plaintiffs' characterization it.

- 101. The allegations in Paragraph 101 do not concern AstraZeneca, and thus AstraZeneca is not required to respond. Further, as to Accord, Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. To the extent an answer is required, AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 101 and on those bases denies them.
- 102. AstraZeneca refers Plaintiffs to the referenced Paragraph IV notice letters for their content and denies Plaintiffs' characterization of them. As to the allegations in the last sentence of Paragraph 102 of the Complaint, they set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 102.

- 103. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. To the extent a response to any allegations related to the "Accord/AstraZeneca agreement" is required, AstraZeneca refers Plaintiffs' to the referenced Paragraph IV certifications and notice letters for their content, denies Plaintiffs' characterization of them, and otherwise denies the allegations in Paragraph 103.
- 104. AstraZeneca admits that it filed three patent infringement lawsuits against Handa in response to Handa's Paragraph IV letters. AstraZeneca refers Plaintiffs to those case numbers and filings for their contents and denies Plaintiffs' characterization of them.
- 105. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. To the extent a response to any allegations related to the "Accord/AstraZeneca agreement" is required, AstraZeneca refers Plaintiffs to the referenced case numbers and all related filings

for their content, denies Plaintiffs' characterization of them, and otherwise denies the allegations in Paragraph 105 of the Complaint.

- 106. AstraZeneca refers Plaintiffs to the referenced ANDAs and case numbers (and all related filings) for their contents and denies Plaintiffs' characterization of them.
- 107. The allegations in Paragraph 107 consist of Plaintiffs' characterization or styling of their allegations, to which no answer is required.
- 108. AstraZeneca refers Plaintiffs to the claim construction proceedings for their content and denies Plaintiffs' characterization of them.
- 109. The allegations in Paragraph 109 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 109.
- 110. The allegations in last sentence in Paragraph 110 of the Complaint do not concern AstraZeneca and thus no response is required. Further, the allegations in last sentence in Paragraph 110 and are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the last sentence of Paragraph 110 and on those bases denies them. As to the remaining

allegations in Paragraph 110, AstraZeneca refers Plaintiffs to the referenced settlement for its contents and denies Plaintiffs' characterization of it.

- 111. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. Further, the allegations in the last sentence in Paragraph 111 of the Complaint do not concern AstraZeneca, are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations in last sentence in Paragraph 111 and on those bases denies them. As to the remaining allegations in Paragraph 111, AstraZeneca refers Plaintiffs to the referenced settlement for its contents and denies Plaintiffs' characterization of it.
- 112. AstraZeneca admits that it did not settle with so-called "Later-Filing Generics" before trial and that the so-called "Later-Filer Seroquel XR Patent Litigation" proceeded to a bench trial in October 2011. AstraZeneca refers Plaintiffs to that litigation for its contents, denies Plaintiffs' characterization of it, and otherwise denies Plaintiffs' allegations in Paragraph 112 of the Complaint.

- 113. AstraZeneca admits that the court found that Torrent's generic Seroquel XR product infringed the '437 patent. As to the remaining allegations in Paragraph 113, AstraZeneca refers Plaintiffs to the referenced litigation for its contents, denies Plaintiffs' characterization of it, and otherwise denies the remaining allegations in Paragraph 113 of the Complaint.
- 114. The allegation in Paragraph 114 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca refers Plaintiffs to the referenced litigation and referenced patent for their contents and denies Plaintiffs' characterization of them. AstraZeneca otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 114 and on those bases denies them.
- 115. AstraZeneca refers Plaintiffs to the referenced application and patent for their contents and denies Plaintiffs' characterization of them.
- 116. As to the first sentence in Paragraph 116 of the Complaint,
 AstraZeneca refers Plaintiffs to the referenced application and patent for their
 contents and denies Plaintiffs' characterization of them. The remaining allegations
 in Paragraph 116 of the Complaint set forth legal conclusions to which no answer
 is required. To the extent an answer is required, AstraZeneca lacks knowledge or

information sufficient to form a belief as to the truth of the allegations in Paragraph 116 and on those bases denies them.

- 117. AstraZeneca refers Plaintiffs to the referenced patents for their contents and denies Plaintiffs' characterization of them. The allegations in Paragraph 117 of the Complaint otherwise set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 117 and on those bases denies them.
- 118. AstraZeneca refers Plaintiffs to the referenced claim construction decision for its contents, denies Plaintiffs' characterization of it, and otherwise denies the allegations in Paragraph 118 of the Complaint.
- 119. The allegations in Paragraph 119 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca refers Plaintiffs to the referenced litigation and opening arguments for their contents, denies Plaintiffs' characterization of them, and otherwise denies the allegations in Paragraph 119 of the Complaint.
- 120. The allegations in Paragraph 120 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca

refers Plaintiffs to the referenced litigation and questioning for their contents, denies Plaintiffs' characterization of them, and otherwise denies the allegations in Paragraph 120 of the Complaint.

- 121. The allegations in Paragraph 121 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 121.
- 122. As to Accord, under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. To the extent a response is required, as to both Handa and Accord, AstraZeneca refers Plaintiffs to the referenced settlements for their contents, denies Plaintiffs' characterization of them, and otherwise denies the allegations in Paragraph 122 of the Complaint.
- 123. As to Accord, under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. To the extent a response is required,

as to both Handa and Accord, AstraZeneca refers Plaintiffs to the referenced settlements for their contents and denies Plaintiffs' characterization of them. The remaining allegations in Paragraph 123 of the Complaint vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 123 of the Complaint.

- 124. As to the first four sentences of Paragraph 124 of the Complaint,
 AstraZeneca refers Plaintiffs to the referenced press release for its contents, denies
 Plaintiffs' characterization of it, and otherwise denies the allegations in the first
 four sentences of Paragraph of the Complaint. The allegations in the last sentence
 of Paragraph 124 of the Complaint are vague and speculative, and to the extent not
 vague and speculative, set forth legal conclusions to which no answer is required.
 To the extent an answer is required to the allegations in the last sentence of
 Paragraph 124 of the Complaint, AstraZeneca denies the allegations.
- 125. The allegations in Paragraph 125 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca refers Plaintiffs to the referenced settlement and cited label for their contents, denies Plaintiffs' characterization of them, and otherwise denies the allegations in Paragraph 125 of the Complaint.

126. As to Accord, under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. To the extent a response is required, as to the first sentence in Paragraph 126 of the Complaint, AstraZeneca refers Plaintiffs to the referenced tentative approval and final approval for Accord's ANDA for their contents and denies Plaintiffs' characterization of them. The second sentence in Paragraph 126 and the allegations related to the "Accord/AstraZeneca agreement" in the last sentence of Paragraph 126 are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required; to the extent an answer is required, AstraZeneca denies these allegations. As to the remaining allegations in Paragraph 126 of the Complaint, AstraZeneca refers Plaintiffs to the referenced tentative approval and final approval for Par's ANDA for their contents and denies Plaintiffs' characterization of them. The remaining allegations in Paragraph 126 are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required; to the extent an answer is required, AstraZeneca denies the remaining allegations in Paragraph 126 of the Complaint.

- 127. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. As to the first sentence in Paragraph 127 of the Complaint, AstraZeneca refers Plaintiffs to the referenced settlement agreements for their contents, denies Plaintiffs' characterization of it, and otherwise denies the allegations in the first sentence of Paragraph 127 of the Complaint. The allegations in the second sentence of Paragraph 127 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 127.
- 128. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. Further, the allegations in Paragraph 128 do not concern AstraZeneca; they also are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca lacks knowledge or

information sufficient to form a belief as to the truth of those allegations, and denies the allegations on those grounds.

- 129. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. The allegations in the first sentence of Paragraph 129 of the Complaint are vague and unclear, and AstraZeneca thus lacks knowledge or information sufficient to form a belief as to the truth of those allegations and on those bases denies them. The remaining allegations in Paragraph 129 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the remaining allegations in Paragraph 129 of the Complaint.
- 130. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. The allegations in Paragraph 130 of the Complaint are vague and speculative, and to the extent not vague and

speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 130 of the Complaint. Moreover, the allegations in the last sentence of Paragraph 130 of the Complaint are false as Plaintiffs were on notice of their purported claims years ago and asserted them in prior litigation. *See, e.g., In re Nexium Antitrust Litig.*, 12-md-02409, D.I. 1496 (D. Mass.), at 14; see also id. D.I. 1458.

AstraZeneca denies the allegations in the last sentence in Paragraph 130 of the Complaint on this ground as well.

- 131. AstraZeneca denies the allegations in Paragraph 131 of the Complaint.
- 132. AstraZeneca denies the allegations in Paragraph 132 of the Complaint.
- 133. The allegations in Paragraph 133 of the Complaint are vague, speculative, and AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 133 and on those bases denies them.
- 134. The allegations in Paragraph 134 of the Complaint are vague, speculative, and AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 134 and on those bases denies them.
- 135. The allegations in Paragraph 135 of the Complaint are vague, speculative, and AstraZeneca lacks knowledge or information sufficient to form a

belief as to the truth of the allegations in Paragraph 135 and on those bases denies them.

- 136. The allegations in Paragraph 136 of the Complaint are vague, speculative, and AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 136 and on those bases denies them.
- 137. The allegations in Paragraph 137 of the Complaint are vague, speculative, and AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 137 and on those bases denies them.
- 138. The allegations in Paragraph 138 of the Complaint are vague, speculative, and AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 138 and on those bases denies them.
- 139. The allegations in Paragraph 139 of the Complaint are vague, speculative, and AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 139 and on those bases denies them.
- 140. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are

DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. To the extent a response is required, AstraZeneca denies the allegations related to the "Accord/AstraZeneca agreement." To the extent a response a required, the allegations in Paragraph 140 of the Complaint are vague, speculative, and AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 140 and on those bases denies them.

- 141. AstraZeneca refers to the cited document for its content and denies Plaintiffs' characterization of it. AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 141 of the Complaint and on that basis denies them.
- 142. AstraZeneca admits it distributed authorized generics with respect to several of the medicines alleged in Paragraph 142.
- 143. For the purported legal proposition in the last sentence of Paragraph 143, AstraZeneca refers Plaintiffs to the cited case for its contents and denies Plaintiffs' characterization of it. The remaining allegations in Paragraph 143 of the Complaint are vague, speculative, and AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 143 and on those bases denies them.

- 144. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. The allegations in Paragraph 144 of the Complaint are vague, speculative, and to the extent not, set forth legal conclusions to which no answer is required. AstraZeneca otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 144 and on those bases denies them.
- 145. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. The allegations in last sentence of Paragraph 145 of the Complaint denied. The remaining allegations in Paragraph 145 of the Complaint are vague, speculative, and AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 145 and on those bases denies them.
- 146. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are

DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. The allegations in Paragraph 146 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 146 of the Complaint.

- 147. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. The allegations in Paragraph 147 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 147 of the Complaint.
- 148. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the

"Accord/AstraZeneca agreement" is required. The allegations in Paragraph 148 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 148 of the Complaint.

- 149. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. The allegations in Paragraph 149 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 149 of the Complaint.
- 150. AstraZeneca refers to the "information available publicly through the FDA" and denies Plaintiffs' characterization of it. AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 150 of the Complaint and on that basis denies them.
- 151. AstraZeneca refers to the "information available publicly through the FDA" and denies Plaintiffs' characterization of it. AstraZeneca lacks knowledge

or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 151 of the Complaint and on that basis denies them.

- 152. AstraZeneca denies the allegations in Paragraph 152 of the Complaint.
- 153. The allegations in Paragraph 153 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 153.
 - 154. AstraZeneca denies the allegations in Paragraph 154 of the Complaint.
- 155. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. To the extent a response is required, AstraZeneca admits that, to its knowledge, Accord launched a generic version of the 400mg strength of Seroquel XR on or about November 1, 2016. AstraZeneca likewise admits that, to its knowledge, Par launched generic 50mg, 150mg, 200mg, and 300mg strengths of Seroquel XR on or about November 1, 2016. As to the allegations in the last two sentences in Paragraph 155 of the Complaint, AstraZeneca refers Plaintiffs to the cited articles for their contents and denes Plaintiffs' characterization of them. The remaining allegations in Paragraph 155 of the Complaint set forth legal conclusions to which no answer is required. To the

extent an answer is required, AstraZeneca denies the remaining allegations in Paragraph 155 of the Complaint.

- 156. The allegations in Paragraph 156 of the Complaint are vague and speculative, and to the extent not, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 156 of the Complaint.
- 157. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 157 of the Complaint.
 - 158. AstraZeneca denies the allegations in Paragraph 158 of the Complaint.
 - 159. AstraZeneca denies the allegations in Paragraph 159 of the Complaint.
 - 160. AstraZeneca denies the allegations in Paragraph 160 of the Complaint.
- 161. AstraZeneca lacks knowledge or information about what is meant by "substantial" sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 161 of the Complaint and on that basis denies them.

 AstraZeneca denies the remaining allegations in Paragraph 161 of the Complaint.
 - trazencea demes the remaining anegations in raragraph 101 of the Complaint.
 - 162. AstraZeneca denies the allegations in Paragraph 162 of the Complaint.

- 163. The allegations in Paragraph 163 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 163 of the Complaint.
- 164. The allegations in Paragraph 164 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 164 of the Complaint.
- 165. The allegations in Paragraph 165 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 165 of the Complaint.
- 166. The allegations in Paragraph 166 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 166 of the Complaint.
- 167. For the legal proposition set forth in Paragraph 167 of the Complaint, AstraZeneca refers Plaintiffs to the case cited for its contents and denies Plaintiffs' characterization of it. The remaining allegations in Paragraph 167 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 167 of the Complaint.

- 168. The allegations in Paragraph 168 of the Complaint are vague and speculative, and AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of those allegations and on those bases denies them.
- 169. The allegations in Paragraph 169 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of those allegations in Paragraph 169 and thus denies them.
- 170. The allegations in Paragraph 170 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of those allegations in Paragraph 170 and thus denies them.
- 171. The allegations in Paragraph 171 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of those allegations in Paragraph 171 and thus denies them.
- 172. The allegations in Paragraph 172 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions

to which no answer is required. To the extent an answer is required, AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of those allegations in Paragraph 172 and thus denies them.

- 173. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. To the extent a response is required, AstraZeneca denies the allegations related to the "Accord/AstraZeneca agreement." The allegations in Paragraph 173 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of those allegations in Paragraph 173 and thus denies them
- 174. The allegations in Paragraph 174 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of those allegations in Paragraph 174 and thus denies them.

- 175. The allegations in Paragraph 175 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of those allegations in Paragraph 175 and thus denies them.
- 176. The allegations in Paragraph 176 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of those allegations in Paragraph 176 and thus denies them.
 - 177. AstraZeneca denies the allegations in Paragraph 177 of the Complaint.
 - 178. AstraZeneca denies the allegations in Paragraph 178 of the Complaint.
 - 179. AstraZeneca denies the allegations in Paragraph 179 of the Complaint.
- 180. AstraZeneca hereby incorporates each preceding and succeeding paragraph as though fully stated herein.
 - 181. AstraZeneca denies the allegations in Paragraph 181 of the Complaint.
- 182. AstraZeneca refers Plaintiffs to the referenced settlement for its contents and denies Plaintiffs' characterization of it. The remaining allegations in Paragraph 182 of the Complaint set forth legal conclusions to which no answer is

required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 182.

- 183. The allegations in Paragraph 183 do not concern AstraZeneca, and thus AstraZeneca is not required to respond. To the extent an answer is required, AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of those allegations, and denies the allegations on those grounds.
- 184. The allegations in Paragraph 184 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 184 of the Complaint.
- 185. The allegations in Paragraph 185 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 185 of the Complaint.
- 186. The allegations in Paragraph 186 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 186 of the Complaint.
- 187. The allegations in Paragraph 187 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 187 of the Complaint.

- 188. AstraZeneca hereby incorporates each preceding and succeeding paragraph as though fully stated herein.
- 189. The allegations in Paragraph 189 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 189 of the Complaint.
- 190. The allegations in Paragraph 190 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 190 of the Complaint.
- 191. The allegations in Paragraph 191 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 191 of the Complaint.
- 192. The allegations in Paragraph 192 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 192 of the Complaint.
- 193. The allegations in Paragraph 193 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions

to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 193 of the Complaint.

- 194. The allegations in Paragraph 194 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 194 of the Complaint.
- 195. The allegations in Paragraph 195 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 195 of the Complaint.
- 196. The allegations in Paragraph 196 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 196 of the Complaint.
- 197. AstraZeneca hereby incorporates each preceding and succeeding paragraph as though fully stated herein.
- 198. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the

"Accord/AstraZeneca agreement" is required. To the extent a response is required, AstraZeneca denies these allegations related to the "Accord/AstraZeneca agreement."

- 199. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. To the extent a response is required, AstraZeneca denies these allegations related to the "Accord/AstraZeneca agreement."
- 200. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. To the extent a response is required, AstraZeneca denies these allegations related to the "Accord/AstraZeneca agreement."
- 201. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement";

accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. To the extent a response is required, AstraZeneca denies the allegations related to the "Accord/AstraZeneca agreement."

- 202. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. To the extent a response is required, AstraZeneca denies these allegations related to the "Accord/AstraZeneca agreement."
- 203. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. To the extent a response is required, AstraZeneca denies these allegations related to the "Accord/AstraZeneca agreement."
- 204. AstraZeneca hereby incorporates each preceding and succeeding paragraph as though fully stated herein.

- 205. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. To the extent a response is required, AstraZeneca denies these allegations related to the "Accord/AstraZeneca agreement."
- 206. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. To the extent a response is required, AstraZeneca denies these allegations related to the "Accord/AstraZeneca agreement."
- 207. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. To the extent a response is required,

AstraZeneca denies these allegations related to the "Accord/AstraZeneca agreement."

- 208. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. To the extent a response is required, AstraZeneca denies these allegations related to the "Accord/AstraZeneca agreement."
- 209. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. To the extent a response is required, AstraZeneca denies these allegations related to the "Accord/AstraZeneca agreement."
- 210. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the

"Accord/AstraZeneca agreement" is required. To the extent a response is required, AstraZeneca denies these allegations related to the "Accord/AstraZeneca agreement."

- 211. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the "Accord/AstraZeneca agreement" is required. To the extent a response is required, AstraZeneca denies these allegations related to the "Accord/AstraZeneca agreement."
- 212. AstraZeneca hereby incorporates each preceding and succeeding paragraph as though fully stated herein.
- 213. The allegations in Paragraph 213 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 213 of the Complaint.
- 214. Under the Court's July 5, 2022 Order (D.I. 178), "[a]ll Counts in the Direct Purchaser Plaintiffs' Consolidated Amended Complaint (D.I. 135) are DISMISSED to the extent they are based on the Accord/AstraZeneca agreement"; accordingly, no response to Plaintiffs' allegations related to the

"Accord/AstraZeneca agreement" is required. To the extent a response is required, AstraZeneca denies the allegations related to the "Accord/AstraZeneca agreement." The remaining allegations in Paragraph 214 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the remaining allegations in Paragraph 214 of the Complaint.

- 215. The allegations in Paragraph 215 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 215 of the Complaint.
- 216. The allegations in Paragraph 216 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 216 of the Complaint.
- 217. The allegations in Paragraph 217 of the Complaint are vague and speculative, and to the extent not vague and speculative, set forth legal conclusions to which no answer is required. To the extent an answer is required, AstraZeneca denies the allegations in Paragraph 217 of the Complaint.

RESPONSE TO PLAINTIFFS' PRAYER FOR RELIEF

- 218. The allegations in Paragraph 218 of the Complaint set forth Plaintiffs' Prayer for Relief and no answer is required. To the extent that an answer is required, denied.
- 219. The allegations in Paragraph 219 of the Complaint set forth Plaintiffs' Prayer for Relief and no answer is required. To the extent that an answer is required, denied.
- 220. The allegations in Paragraph 220 of the Complaint set forth Plaintiffs' Prayer for Relief and no answer is required. To the extent that an answer is required, denied.
- 221. The allegations in Paragraph 221 of the Complaint set forth Plaintiffs' Prayer for Relief and no answer is required. To the extent that an answer is required, denied.
- 222. The allegations in Paragraph 222 of the Complaint set forth Plaintiffs' Prayer for Relief and no answer is required. To the extent that an answer is required, denied.
- 223. The allegations in Paragraph 223 of the Complaint set forth Plaintiffs' Prayer for Relief and no answer is required. To the extent that an answer is required, denied.

RESPONSE TO PLAINTIFFS' JURY TRIAL DEMAND

The allegations in this Paragraph set forth Plaintiffs' Jury Trial Demand and no answer is required.

AFFIRMATIVE DEFENSES

Without assuming any burden that it would not otherwise bear, AstraZeneca asserts the following defenses and/or affirmative defenses to the Complaint.

Further, AstraZeneca reserves all affirmative defenses under Federal Rule of Civil Procedure 8(c) and any other defenses, at law or in equity, that may now exist or in the future be available based on discovery and further factual investigation in this case.

First Defense

1. The Complaint fails, in whole or in part, to state a claim upon which relief may be granted.

Second Defense

2. Plaintiffs' claims are barred in whole or in part by the applicable statutes of limitation and/or the doctrines of laches, waiver, and/or estoppel. Plaintiffs allegations date back to at least 2011, they knew of their purported claims years ago, and they asserted them in prior litigation. *See, e.g., In re Nexium Antitrust Litig.*, 12-md-02409, D.I. 1496 (D. Mass.), at 14; *see also id.* D.I. 1458.

Third Defense

3. Plaintiffs' claims are barred, in whole or in part, because they seek damages that are duplicative of damages sought by other plaintiffs in these actions, and such duplicative recovery would violate the Due Process Clauses of the Fifth and Fourteenth Amendments to the Constitution of the United States.

Fourth Defense

4. Plaintiffs' claims are barred in whole or in part because any award of treble damages or punitive or exemplary damages against AstraZeneca based on the alleged conduct would violate the Due Process Clauses of the Fifth and Fourteenth Amendments to the Constitution of the United States.

Fifth Defense

5. Plaintiffs' claims are barred in whole or in part because Plaintiffs failed to make reasonable efforts to mitigate damages, if any, allegedly suffered as a result of the conduct they allege.

Sixth Defense

6. To the extent the Complaint could be read as seeking punitive damages, such damages are not available in this action.

Seventh Defense

7. Plaintiffs' claims are barred in whole or in part because Plaintiffs have not suffered any actual injury or damage as a result of any of the alleged conduct.

Eighth Defense

8. AstraZeneca incorporates by reference any defenses applicable to it that are asserted by any other defendant to the Complaint as if set forth fully herein.

PRAYER FOR RELIEF

WHEREFORE, AstraZeneca hereby requests that Plaintiffs' Complaint be dismissed in its entirety, with prejudice; that any and all of Plaintiffs' claims for damages or other relief of any sort or nature be denied; that AstraZeneca be awarded costs, disbursements, and reasonable attorneys' fees; and that AstraZeneca be awarded such other and further relief as this Court may deem just and proper.

Dated: August 18, 2022

OF COUNSEL:

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